

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A pharmaceutical composition for a chewable tablet, comprising in admixture:
an alginic acid or a salt thereof;
a water-soluble carbonate radical precursor;
a calcium salt;
a first bulk sweetener;
a binding agent; and
wherein said calcium salt and either or both of said first bulk sweetener and said binding agent are blended via wet granulation prior to admixture with said alginic acid or salt thereof and said carbonate radical precursor.
2. (Original) The chewable tablet according to claim 1, wherein said alginic acid or salt thereof is present in an amount from about 70 to about 500 mg per tablet.
3. (Original) The chewable tablet according to claim 2, wherein said alginic acid or salt thereof is present in an amount from about 200 to about 400 mg per tablet.
4. (Original) The chewable tablet according to claim 3, wherein said alginic acid or salt thereof is present in an amount from about 200 to about 300 mg per tablet.
5. (Original) The chewable tablet according to claim 1, wherein said carbonate radical precursor is selected from the group consisting of a carbonate of an alkali metal, a bicarbonate of an alkali metal, a carbonate of an alkaline earth metal, a bicarbonate of an alkaline earth metal, and combinations thereof.
6. (Original) The chewable tablet according to claim 5, further comprising an alkali metal or alkaline earth metal of hexametaphosphate, wherein said alkali metal is selected from the group consisting of sodium or potassium and said alkaline earth metal is selected from the group consisting of calcium, magnesium, and manganese.

7. (Original) The chewable tablet according to claim 5, wherein said carbonate radical precursor is selected from the group consisting of potassium bicarbonate, sodium bicarbonate, and a combination thereof.

8. (Original) The chewable tablet according to claim 7, wherein said carbonate radical precursor is present in an amount from about 50 to about 200 mg per tablet.

9. (Original) The chewable tablet according to claim 8, wherein said carbonate radical precursor is present in an amount from about 70 to about 160 mg per tablet.

10. (Original) The chewable tablet according to claim 1, wherein said calcium salt is selected from the group consisting of calcium citrate, calcium maleate, calcium citrate maleate, calcium carbonate, calcium lactate, calcium glyceryl phosphate, calcium phosphate, and combinations thereof.

11. (Original) The chewable tablet according to claim 10, wherein said calcium salt is calcium carbonate.

12. (Original) The chewable tablet according to claim 1, wherein said calcium salt is present in an amount from about 100 to about 1000 mg free calcium per tablet.

13. (Original) The chewable tablet according to claim 12, wherein said calcium salt is present in an amount from about 250 to about 1000 mg free calcium per tablet.

14. (Original) The chewable tablet according to claim 13, wherein said calcium salt is present in an amount of about 500 mg free calcium per tablet.

15. (Original) The chewable tablet according to claim 1, wherein said binding agent is selected from the group consisting of a starch, a natural gum, a low viscosity cellulosic derivative, a medium viscosity cellulosic derivative, a polymer, and combinations thereof.

16. (Original) The chewable tablet according to claim 15, wherein said binding agent is a starch selected from the group consisting of corn starch, modified corn starch, wheat starch, modified wheat starch, Starch 1500, pre-gelatinized starch, and combinations thereof.

17. (Original) The chewable tablet according to claim 16, wherein said starch is corn starch or modified corn starch.

18. (Original) The chewable tablet according to claim 15, wherein said starch is present in an amount from about 1 % to about 15 % of the tablet weight.

19. (Original) The chewable tablet according to claim 15, wherein the binding agent is a low-viscosity cellulosic derivative selected from the group consisting of carbomer, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, microcrystalline cellulose, carboxymethylcellulose, hydroxyethylcellulose, methylcellulose, and combinations thereof.

20. (Original) The chewable tablet according to claim 19, wherein said cellulosic derivative is present in an amount from about 1 % to about 10 % of the tablet weight.

21. (Original) The chewable tablet according to claim 15, wherein said binding agent is a natural gum selected from the group consisting of pectin, gelatin, gum arabic, acacia, carrageenan, guar, tragacanth, and combinations thereof.

22. (Original) The chewable tablet according to claim 21, wherein said natural gum is present in an amount from about 0.5 % to about 7 % of the tablet weight.

23. (Original) The chewable tablet according to claim 1, wherein said binding agent is selected from the group consisting of povidone, maltodextrin, mannitol, sorbitol, a polaxomer, a polydextrose, polyethylene glycol, a polymethacrylate, and combinations thereof.

24. (Original) The chewable tablet according to claim 1, wherein said binding agent is selected from the group consisting of polyethylene oxide, sodium carboxymethylcellulose, polyvinyl alcohol, calcium polycarbophil, HPMC (medium viscosity), and polyethylene glycol (PEG); or combinations thereof and/or combinations with other binding agents.

25. (Original) The chewable tablet according to claim 1, wherein said first bulk sweetener is a sugar selected from the group consisting of dextrose, sucrose, lactose, confectionery sugar, powdered sugar, dextrin, fructose, glucose, polydextrose, sorbitol, maltitol, maltose, mannitol, xylitol, and combinations thereof.

26. (Original) The chewable tablet according to claim 24, wherein said first bulk sweetener is a sugar selected from the group consisting of dextrose, sucrose, and a combination thereof.

27. (Original) The chewable tablet according to claim 1, wherein said first bulk sweetener is a polyol selected from the group consisting of mannitol, sorbitol, xylitol, maltitol, maltose, polydextrose, and combinations thereof.

28. (Original) The chewable tablet according to claim 27, wherein said polyol is selected from the group consisting of mannitol, sorbitol, and a combination thereof.

29. (Original) The chewable tablet according to claim 1, wherein said first bulk sweetener is wet granulated with said calcium salt, and wherein said first bulk sweetener is present in an amount from about 10 % to about 30 % of the tablet weight.

30. (Original) The chewable tablet according to claim 26, wherein said first bulk sweetener is a sugar wet granulated with said calcium salt, and wherein said sugar is present in an amount from about 15 % to about 25 % of the tablet weight.

31. (Original) The chewable tablet according to claim 1, wherein said first bulk sweetener is a sugar selected from the group consisting of dextrose; sucrose; lactose; confectionery sugar; powdered sugar; a polyol selected from the group consisting of mannitol, sorbitol, xylitol, erythritol, maltitol, maltose, polydextrose, and combinations thereof; and combinations thereof.

32. (Original) The chewable tablet according to claim 1, further comprising a second bulk sweetener, wherein said second bulk sweetener is a sugar selected from the group consisting of dextrose; sucrose; lactose; confectionery sugar; powdered sugar; a polyol selected from the group consisting of mannitol, sorbitol, xylitol, erythritol, maltitol, maltose, polydextrose, and combinations thereof; and combinations thereof.

33. (Original) The chewable tablet according to claim 32, wherein said second bulk sweetener is selected from the group consisting of dextrose, sucrose, lactose, confectionery sugar, powdered sugar, and combinations thereof.

34. (Original) The chewable tablet according to claim 32, wherein said second bulk sweetener is a polyol selected from the group consisting of mannitol, sorbitol, xylitol, erythritol, maltitol, maltose, polydextrose, and combinations thereof.

35. (Original) The chewable tablet according to claim 32, wherein said second bulk sweetener is a polyol selected from the group consisting of mannitol, sorbitol, and a combination thereof.

36. (Original) The chewable tablet according to claim 32, wherein said second bulk sweetener is a combination of dextrose and a polyol selected from the group consisting of mannitol, sorbitol, and a combination thereof.

37. (Original) The chewable tablet according to claim 32, wherein said second bulk sweetener is present in an amount from about 200 mg to about 1000 mg per tablet or 0.8 % to 40 % by weight of the tablets.

38. (Original) The chewable tablet according to claim 1, further comprising a second bulk sweetener, and wherein said first bulk sweetener and said second bulk sweetener are not the same; and further wherein a portion of the first or second bulk sweetener is optionally replaced by gelatin or casein.

39. (Original) The chewable tablet according to claim 1, wherein said first bulk sweetener is selected from the group consisting of sucrose, mannitol, dextrose, and combinations thereof and the second bulk sweetener is selected from the group consisting of mannitol, sorbitol, dextrose, and combinations thereof.

40. (Original) The chewable tablet according to claim 1, wherein both said binding agent and said first bulk sweetener are blended with the calcium salt by wet granulation.

41. (Original) The chewable tablet according to claim 40, wherein said binding agent is present in an amount from about 1 % to about 15 %, wherein said first bulk sweetener is present in an amount from about 10 % to about 30 %, and wherein said calcium salt is present in an amount from about 10 % to about 50 % by weight of tablet.

42. (Original) The chewable tablet according to claim 41, wherein said binding agent is corn starch, wherein said first bulk sweetener is sucrose, and wherein said calcium salt is calcium carbonate.

43. (Original) The chewable tablet according to claim 1, further comprising talc, wherein said talc is present in an amount from about 0.5 % to about 3 % of the tablet weight.

44. (Original) The chewable tablet according to claim 1, further comprising an intense sweetener, wherein said intense sweetener is selected from the group consisting of acesulfame-K, saccharin, aspartame, sucralose, and combinations thereof.

45. (Original) The chewable tablet according to claim 1, further comprising an intense sweetener, wherein said intense sweetener is present in an amount from about 0.02 % to about 0.12 % of the tablet weight.

46. (Original) The chewable tablet according to claim 1, further comprising a mineral oil, wherein the mineral oil is present in an amount up to about 1 % of the tablet weight.

47. (Original) The chewable tablet according to claim 1 wherein a portion of the water soluble carbonate radical precursor is replaced with sodium or potassium phosphate.

48. (Original) A method of calcium supplementation to a mammal in need thereof, comprising administering an effective amount of a composition according to any one of claims 1 to 47.

49. (Currently Amended) A method of reducing gastric reflux in a human in need thereof, comprising administering to said human an effective amount of a composition according to ~~any one of claims 1 to 47~~ claim 1.

50. (Currently Amended) A method of reducing heartburn in a human in need thereof, comprising administering to said human an effective amount of a composition according to ~~any one of claims 1 to 47~~ claim 1.

51. (Currently Amended) A method of reducing the incidence of gastric reflux in the esophageal cavity in a human for a period of time following post ingestion of a meal causing gastric reflux in said human for a time period of about 60 to about 480 minutes, comprising administering to said human an effective amount of a composition according to ~~any one of claims 1 to 47~~ claim 1.

52. (Original) The method according to claim 51, wherein said time period is from about 120 to about 300 minutes.

53. (Original) The method according to claim 52, wherein the time period is about 120 to 180 minutes

54. (Original) The method according to Claim 51 wherein the pH of the esophageal cavity is maintained at a pH of about 4.0 or higher.

55. (Currently Amended) A method of maintaining a pH of about 4.0 or higher in the esophageal cavity of a human for a time period from about 60 to about 480 minutes, comprising: administering to said human an effective amount of a composition according to ~~any one of claims 1 to 47~~ claim 1.

56. (Original) The method according to claim 55, wherein said pH is 5.0 or higher.

57. (Original) The method according to claim 55, wherein said time period is from about 120 to about 300 minutes.

58. (Original) The method according to claim 57 wherein said time period is about 120 to 180 minutes.

59. (Original) A pharmaceutical composition comprising calcium carbonate, sugar, mannitol, corn starch, alginic acid, and a carbonate radical precursor selected from the group consisting of potassium bicarbonate, sodium bicarbonate and a combination thereof, wherein the composition is in the form of a chewable tablet.

60. (Original) The composition according to claim 59, wherein a portion of the carbonate radical precursor is replaced by sodium or potassium phosphate.

61. (Original) The composition according to claim 59, wherein said alginic acid is present in an amount of about 8 %; wherein said potassium bicarbonate is present in an amount of about 6%; wherein said calcium carbonate is present in an amount of about 20 % w/w; wherein said starch is present in amount about 5 %; wherein said sugar is present in an amount about 26 %; and wherein said mannitol is present in an amount of about 32 % by weight of the tablet.

62. (Original) The composition according to claim 61, further comprising an intense sweetener, a talc, a light mineral oil, sodium hexametaphosphate, and calcium stearate, wherein said intense sweetener is present in an amount of about 0.1 %, wherein said talc is present in an amount about

1 %, wherein said light mineral oil present in an amount about 0.6 %, wherein said sodium hexametaphosphate is present in an amount about 0.2 %, and wherein said calcium stearate present in an amount of about 0.5 % by weight of the tablet.

63. (Original) The composition according to claim 1, wherein said carbonate radical precursor is a compound different than that of said calcium salt.

64. (Original) A pharmaceutical composition for a chewable tablet formed by a process comprising the following steps:

- providing an alginic acid or a salt thereof;
- providing a water-soluble carbonate radical precursor;
- providing a calcium salt;
- providing a first bulk sweetener;
- providing a binding agent;

mixing said calcium salt and either or both of said bulk sweetener and said binding agent via wet granulation to form a mixture; and

blending said mixture with said alginic acid or salt thereof, said carbonate radical precursor, and with either said first bulk sweetener or said binding agent if not previously mixed with the calcium salt.

65. (Original) The composition of claim 64, wherein said alginic acid or salt thereof is provided in an amount from about 70 to about 500 mg per tablet.

66. (Original) The composition of claim 64, wherein said carbonate radical precursor provided is selected from the group consisting of a carbonate of an alkali metal, a bicarbonate of an alkali metal, a carbonate of an alkaline earth metal, a bicarbonate of an alkaline earth metal, and combinations thereof.

67. (Original) The composition of claim 66, wherein said carbonate radical precursor provided is selected from the group consisting of potassium bicarbonate, sodium bicarbonate, and a combination thereof.

68. (Original) The composition of claim 66, wherein said carbonate radical precursor is partially replaced by sodium or potassium phosphate in a % w/w amount.

69. (Currently Amended) The composition of claim 67 [[or 68]], wherein said carbonate radical precursor is provided in an amount from about 50 to about 200 mg per tablet.

70. (Original) The composition of claim 64, wherein said calcium salt provided is selected from the group consisting of calcium citrate, calcium maleate, calcium citrate maleate, calcium carbonate, calcium lactate, calcium glyceryl phosphate, calcium phosphate, and combinations thereof.

71. (Original) The composition of claim 64, wherein said calcium salt provided is calcium carbonate.

72. (Original) The composition of claim 64, wherein said calcium salt is provided in an amount from about 100 to about 1000 mg free calcium per tablet.

73. (Original) The composition of claim 64, wherein said binding agent provided is selected from the group consisting of a starch, a polymer, a natural gum, a low viscosity cellulosic derivative, a medium viscosity cellulosic derivative, and combinations thereof.

74. (Original) The composition of claim 64, wherein said first bulk sweetener provided is a sugar selected from the group consisting of dextrose, sucrose, lactose, confectionery sugar, powdered sugar, dextrin, fructose, glucose, polydextrose, sorbitol, malititol, maltose, mannitol, xylitol, and combinations thereof; and further wherein the a portion of the first bulk sweetener is optionally replaced by gelatin or casein.

75. (Original) The composition of claim 64, wherein said first bulk sweetener provided is in an amount about 10 % to about 30 % of the tablet weight.

76. (Original) The composition of claim 64, which further comprises the addition of magnesium or aluminum cation in the form of an antacid.

77. (Original) The composition of claim 76, wherein the magnesium or aluminum antacid is selected from the group consisting of magnesium carbonate, magnesium oxide, magnesium hydroxide, magnesium aluminate, aluminum hydroxide, or aluminum magnesium hydroxide; or combinations thereof.

78. (Original) A pharmaceutical composition for a chewable tablet, comprising in admixture:

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- an alginic acid or a salt thereof;
- a water-soluble carbonate radical precursor;
- a calcium salt;
- a first bulk sweetener; and
- a binding agent.

79 to 216. (Cancelled)